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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,526	11/14/2003	Massi E. Kiani	MASIMO.377A	2220
20995	7590	03/10/2006		EXAMINER
		KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA. 92614		BERHANU, ETSUB D
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/714,526	KIANI ET AL.	
	Examiner Etsub D. Berhanu	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11/14/2003.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-31 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 14 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/22/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: elements 200, 210, 202, 207 and 270 of Figure 2; element 422 of Figure 4; element 569 of Figure 5; element 832 of Figure 8A; element 900 of Figures 9A-D; elements 1002 and 1004 of Figure 10A and 10B. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: elements 1318 and 1332 in section [0061] on page 16. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/671,179 further in view of Oosta'480 (US Patent No. 5,725,480). Claims 1 and 2 of the copending application disclose a monitor and method comprising a primary input, a parameter input, a compensation relationship of the primary input, parameter input and a compensated measurement, and a processor configured to output the compensated measurement from the primary input and parameter input using the compensation relationship. Claims 1 and 10 of the current application disclose the same monitor and method except for the primary input deriving a spectral characteristic of a tissue site.

Oosta'480 teaches that a number of methods exist for non-invasively detecting and monitoring biologically significant compounds in a subject, including measuring the effect of the compound on the absorbance, reflectance or transmittance of non-ionizing radiation that illuminates a portion of the subject (col. 1, lines 15-20).

It would have been obvious to one of ordinary skill in the art to modify the primary input of the copending application to measure the spectral characteristic of a tissue site, as taught by Oosta'480, since the spectral characteristic of the tissue site can be used to detect and monitor a biologically significant compound in a subject.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Lines 2-4 of claim 1 fail to define the structure of the monitor and claims 2-9 fail to further limit the structure of the monitor.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted or an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1, 10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Oosta et al.'480.

Oosta et al.'480 discloses a monitor and method comprising: a spectral characteristic of a tissue site derivable from a primary input; deriving a physiological measurement from the characteristic; at least

one parameter determinable from a secondary input; a compensation relationship of said spectral characteristic, said parameter and a compensated oxygen saturation measurement, and a processor configured to output said compensated measurement utilizing said compensation relationship (col. 2, lines 26-40, 56-64 and col. 5, lines 6-36).

9. Claims 1, 8, 10, 11, 16, 20, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacques et al.'549 (US Patent No. 6,421,549).

Regarding claims 1, 8, 20, 22 and 23, Jacques et al.'549 discloses a monitor comprising: a spectral characteristic of a tissue site derivable from a primary input (Figure 2, pulsatile factor R); at least one parameter relevant to measuring oxygen saturation determinable from a secondary input (col. 11, lines 1-8); a compensation relationship of said spectral characteristic, said parameter and a compensated oxygen saturation measurement, and a processor configured to output said compensated measurement utilizing said compensation relationship (col. 11, lines 9-22); calibration data relating the spectral property and at least one parameter to a compensated oxygen saturation measurement, wherein the calibration data represents a multidimensional calibration surface (Figure 3); a look-up table having the spectral property and at least one parameter as inputs (col. 9, lines 25-36); and means for correcting an uncompensated oxygen saturation measurement so as to derive a compensated oxygen saturation measurement (col. 8, lines 29-37).

Regarding claims 10, 11 and 16, Figure 1 of Jacques et al.'549 discloses a monitoring method comprising the steps of: inputting a sensor signal responsive to a spectral characteristic of a tissue site (Probe Measurements 20); deriving a physiological measurement from the characteristic (Pusatile Circuitry for calculating pulsatile factor R which is used to determine arterial blood oxygen saturation as described in col. 7, lines 17-22); deriving a parameter from the sensor signal, wherein the physiological measurement has a dependency on the parameter (volume fraction of blood in the tissue f_v and mixed blood oxygen saturation S_mO_2); determining a relationship between the spectral characteristic and the

parameter (Calibration Grid Map 30); compensating the physiological measurement for the parameter utilizing the relationship (Calibration Curves 40 and 50); storing a multidimensional calibration surface (Figure 3); and looking-up the physiological measurement from the calibration surface according to the spectral characteristic (col. 8, lines 29-37).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 2, 6, 12, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacques et al.'549, as applied to claims 1, 10 and 20.

Jacques et al.'549 discloses all the elements of the current invention, as discussed in paragraph 9, except for baseline calibration data relating a spectral characteristic to an uncompensated physiological measurement, and means for modifying baseline calibration data according to a parameter. Further, Jacques et al.'549 discloses an algorithm that is used to directly compute a physiological measurement

from the spectral characteristics and parameter inputs (Figure 2 and col. 10, lines 38-56) and a computational model for calculating R vs. S_aO_2 calibration curves (col. 12 line 57 – col. 21 line 29).

However, all or part of a look-up table, calibration data modification and baseline calibration data may be replaced by or combined with a mathematical formula or algorithm, theoretically or experimentally derived, that is used to compute calibration data or directly compute a physiological measurement from the spectral characteristics and parameter inputs, as these are merely alternate equivalent expedients, as discussed in section [0045] on page 11 of the instant application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute baseline calibration data and means for modifying the baseline calibration data for the algorithms of Jacques et al.'549, as it is generally held to be within the skill of the art to substitute alternate equivalent expedients.

It is noted that the criticality of the baseline calibration data and means for modifying the baseline calibration data were not implied in the specifications of the current application.

Allowable Subject Matter

13. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a monitor or method comprising a spectral characteristic of a tissue site derivable from a primary input, at least one parameter relevant to measuring oxygen saturation determinable from a secondary input, a compensation relationship of said spectral characteristic, said parameter and a compensated oxygen saturation measurement, and a processor configured to output said compensated measurement utilizing said compensation relationship, further including either: a sensitivity control; carboxyhemoglobin concentration as the at least one parameter and a correction comprising a function which distinguishes carboxyhemoglobin from oxyhemoglobin; calibration data representing a plurality of wavelength-dependent compensation

calibration curves and a wavelength determination in response to at least one parameter so as to select a sensor wavelength and a corresponding one of said compensation calibration curves; comparing an SpO₂ value to an S_aO₂ value so as to determine a difference, and modify calibration data so as to reduce the difference; using a hemoglobin constituent measurement as a parameter and distinguishing the constituent from oxyhemoglobin and reduced hemoglobin and adjusting an oxygen saturation measurement accordingly; storing wavelength-dependent calibration data, selecting an active portion of calibration data according to a wavelength, and adjusting a sensor so that a spectral characteristic corresponds to the wavelength; identifying a range of the physiological measurement and specifying a wavelength according to the range; or the physiological measurement corresponds to oxygen saturation and the wavelength has a first value at normal oxygen saturation levels and a second value below normal oxygen saturation levels.

14. Claims 3-5, 7, 9, 13, 15, 17-19 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571.272.4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB



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PRIMARY EXAMINER